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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LAWRENCE XAVIER WEBB, M.D.

Appeal 2009-003981
Application 09/553,683
Technology Center 3700

Decided: March 10, 2010

Before STEVEN D.A. MCCARTHY, STEFAN STAICOVICI and
FRED A. SILVERBERG, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Lawrence Xavier Webb, M.D. (Appellant) appeals under 35 U.S.C. § 134 (2002) from the Examiner's decision rejecting claims 30, 32, 34-57, 59, and 61-75.¹ Claims 1-27, 31, 33, 58, and 60 have been canceled and claims 28 and 29 have been allowed by the Examiner. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

THE INVENTION

Appellant's invention relates to a surgical targeting system 1 including an imaging radiation translucent antimicrobial drape 9 and image radiation opaque indicia 21 affixed to the drape 9. Spec. 20, ll. 6-7 and 22-24 and fig. 1.

Claim 30 is representative of the claimed invention and reads as follows:

30. A sterile surgical drape comprising:
- a radio-lucent sheet;
 - adhesive on a major surface of the radio-lucent sheet;
 - a radio-opaque pattern on the sterile surgical drape,

¹ We note that the Claims Appendix includes two claims numbered as "72," which depend from independent claim 71. App. Br. 18. In the Communication filed Jun. 14, 2004, Appellant submitted two separate and distinct claims "72." Accordingly, for the purpose of this appeal, we shall refer to the first instance of claim 72 as "72(1)" and the second instance of claim 72 as "72(2)." Furthermore, because claim 73 depends from claim 72, and there are two claims numbered as "72", it is unclear from which of the two claims 72, namely, 72(1) or 72(2), does claim 73 depend. These informalities are deserving of correction in the event of any further prosecution that may occur.

wherein the radio-opaque-pattern comprises a perimeter, an interior within the perimeter, and a plurality of intersections distributed within the interior of the radio-opaque pattern; and

a plurality of unique radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of unique radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern, and wherein a plurality of uniquely labeled intersections are provided in the interior of the radio-opaque pattern on the sterile surgical drape.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Muller	US 4,899,762	Feb. 13, 1990
Krupnick	US 5,052,035	Sep. 24, 1991
Mosby	US 5,260,985	Nov. 9, 1993

The following rejections are before us for review:

The Examiner rejected claims 30, 32, 34-38, 41-43, 47-49, 53-57, 59, 61, 67, and 71-75 under 35 U.S.C. § 103(a) as unpatentable over Muller and Krupnick.^{2,3,4}

² For the purpose of this appeal, we shall consider that this rejection includes both the first instance of claim 72, namely, 72(1) and the second instance of claim 72, namely, 72(2). *See also* fn [1].

³ In the Final Rejection, mailed Mar. 8, 2005, in the Claim Rejections section at 2 (Final Rejection 2), the Examiner includes claims 58 and 60 in the rejection. However, claims 58 and 60 were canceled in the Amendment filed Jun. 14, 2004. Accordingly, claims 58 and 60 will not be considered in this appeal.

The Examiner rejected claims 39, 40, 44-46, 50-57, 59, 61-66, and 68-70 under 35 U.S.C. § 103(a) as unpatentable over Muller, Krupnick, and Mosby.

THE ISSUES

Appellant argues that neither Muller nor Krupnick discloses a plurality of radio-opaque labeled intersections such that the radio-opaque labels are located within the interior of the radio-opaque pattern. *See* Br. 4 and 5. In other words, Appellant argues that the radio-opaque pattern of Muller and Krupnick does not include radio-opaque labels at each intersection point, but rather at the edges or the perimeter of the radio-opaque pattern. *Id.*

In response, the Examiner takes the position that labeling each intersection, so as to uniquely identify it, does not appear to provide any criticality over labeling only the perimeter. Ans. 4. The Examiner explains that labeling each intersection,

... would have been obvious to one skilled in the art at the time that the invention was made as an alternative functional equivalent resulting the same end result which is unique identification of the intersections. In other words, regardless whether the labels are at the periphery of the drape or at each intersection itself, the purpose is to identify the intersection and thereby they constitute functional equivalents.

⁴ With respect to claim 59, on page 3 of the Examiner's Answer, mailed Apr. 8, 2008, the Examiner has omitted to include claim 59 in this rejection. However, for the purpose of this appeal, we shall consider this to be a typographical error on the part of the Examiner, and as such, we shall consider claim 59 to be part of this rejection.

Final Rejection, mailed Feb. 11, 2004, p. 2-3.

Appellant counters that:

[A]ccurate identification of the surgical site may be facilitated by including labels at intersections within the interior of the pattern. Actual physical labels located at intersections within the interior of the pattern do not provide the advantages of the labeled intersections and, therefore, cannot be "functional equivalents" to imaginary labels that do not physically exist, but that must, instead, be derived from labels at the edges of a pattern.

Br. 5.

Accordingly, the first issue presented for our consideration in the instant appeal is as follows:

Would the combined teachings of Muller and Krupnick have prompted a person of ordinary skill in the art to provide a unique radio-opaque label at each intersection point of a plurality of intersections of a radio-opaque pattern?

Appellant further argues that neither Muller nor Krupnick discloses a sterile surgical drape having "a central cutout and a slit extending outward from the central cutout," as called for by independent claims 53 and 62. Br. 5 and 6. In response, the Examiner takes the position that the opening 40 and the line 26 of Krupnick constitute a cutout and slit. Furthermore, the Examiner notes that, "in the broadest reasonable interpretation . . . when a biopsy needle enters the surgical drape there is necessarily a cutout." Ans. 4. Accordingly, the second issue presented for our consideration in the instant appeal is as follows:

Do the combined teachings of Muller and Krupnick disclose a sterile surgical drape having “a central cutout,” as called for by independent claims 53 and 62?

Appellant further argues that the combined teachings of Muller, Krupnick, and Mosby do not disclose a “cylindrical portion adapted to fit over a finger,” as recited in claims 45 and 51, or a “hemispherical end portion located at one end of the cylindrical portion,” as recited in claims 46 and 52. In response, the Examiner takes the position that Mosby discloses the use of radio-opaque circles on “breast procedures or on body parts resembling cylindrical or conical configurations such as a finger.” Ans. 4. Moreover, pointing to Mosby’s reference to “human body parts,” the Examiner concludes that the “drape is capable of being used at any body part of interest, which resembles cylindrical or conical configurations such as a finger.” Ans. 6. Hence, the third issue presented for our consideration in the instant appeal is as follows:

Do the combined teachings of Muller, Krupnick, and Mosby disclose a “cylindrical portion adapted to fit over a finger,” as recited in claims 45 and 51, and a “hemispherical end portion located at one end of the cylindrical portion,” as recited in claims 46 and 52?

Finally, Appellant argues that the combined teachings of Muller, Krupnick, and Mosby do not disclose the step of “applying a sterile surgical drape to a patient by *unrolling* a cylindrical portion of the sterile surgical drape onto an extremity, finger or other appendage of the patient,” as called for by independent claim 64 (emphasis added).

Accordingly, the fourth issue presented for our consideration in the instant appeal is whether the combined teachings of Muller, Krupnick, and

Mosby disclose the limitation “applying a sterile surgical drape to a patient by unrolling a cylindrical portion of the sterile surgical drape onto an extremity, finger or other appendage of the patient,” as called for by independent claim 64.

SUMMARY OF DECISION

We AFFIRM-IN-PART.

FINDINGS OF FACT

The following enumerated findings of facts (FF) are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

1. Muller discloses a surgical drape 10 having a plurality of horizontal and vertical radio-opaque grid lines 53 forming a grid pattern. Muller, col. 6, ll. 22-23 and fig. 1.
2. Muller further discloses using letters and numbers located at the top and right edge of the drape, respectively, to uniquely identify intersection points of the grid pattern formed by radio-opaque grid lines 53. Muller, fig. 1.
3. Krupnick discloses a radiographic marker sheet 20 (surgical drape) having a plurality of horizontal and vertical radio-opaque grid lines 32, 30 forming a grid pattern. Krupnick, col. 3, ll. 46-51.

4. Krupnick labels the grid pattern using numbers and letters located at the top and left edge of the pattern. Krupnick, fig. 1.
5. A person of ordinary skill in the art would have readily recognized that each intersection point in a grid pattern is uniquely identified by the letter and number corresponding to the perimetrically-labeled intersecting lines that form the intersection point.
6. Mosby discloses a localization device constructed from a pliable and transparent adhesive sheet that is imprinted with radiopaque and visible grid lines numbered and lettered in more than one axis so as to conform to the outline of a subject structure, *i.e.*, human breast or other human body parts. Mosby, col. 5, ll. 9-12; col. 6, ll. 38-56, and fig. 1.
7. The localization device of Mosby includes a cylindrical portion and a hemispherical end portion located at one end of the cylindrical portion. Mosby, fig. 4.

PRINCIPLES OF LAW

Claim Construction

When construing claim terminology in the United States Patent and Trademark Office, claims are to be given their broadest reasonable interpretation consistent with the specification, reading claim language in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Printed Matter

In dealing with printed matter, “the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.” *In re Gulack*, 703 F.2d 1381, 1386 (Fed. Cir. 1983). “[W]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.” *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004).

OPINION

Issue (1)

Appellant argues the rejection under 35 U.S.C. § 103(a) of claims 30, 32, 34-38, 41-43, 47, 48, 57, 59, 61, and 71-75 together as a group. Br. 3-5. Accordingly, we have selected claim 30 as the representative claim to decide the appeal, with claims 32, 34-38, 41-43, 47, 48, 57, 59, 61, and 71-75, standing or falling with claim 30. *See* 37 C.F.R. § 41.37(c)(1)(vii)(2009).

As noted above, both Muller and Krupnick uniquely identify an intersection point using the letters and numbers along the perimeter of the pattern to form unique identifiers. FF 1-4. Each intersection point in a grid pattern is uniquely identified by the letter and number corresponding to the perpendicular lines forming the intersection point. FF 5. For example, as shown in Figure 1 of Muller, the index line 52 of Muller crosses the grid pattern at an intersection point uniquely identified by the letter “d” and the number 8, that is, as “d8.” Although each intersection point is not specifically labeled, nonetheless, we find that each intersection point of Muller’s or Krupnick’s grid is uniquely identified. In other words,

Appellant's claimed surgical drape is nothing more than the surgical drape of Muller and Krupnick where the letters and numbers labeled along the perimeter of the pattern have been replaced with markings at each intersection point so as to be individually labeled. Hence, modifying the labeled grid pattern of Muller and Krupnick to include individual labeling of each intersection point rather than perimetrically labeling the grid pattern would not have been uniquely challenging to a person of ordinary skill in the art, because it is no more than the substitution of one labelling scheme for another. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). "When a work is available in one field of endeavor, design incentives and other market forces can prompt *variations* of it, either in the same field or a different one. If a person of ordinary skill can implement a *predictable variation*, § 103 likely bars its patentability." *Id.* Emphasis added. In this case, we find that labeling each intersection point of the grid pattern of the surgical drape of Muller and Krupnick is merely a predictable variation that a person of ordinary skill in the art would have recognized.

Furthermore, the label of each intersection point is merely a representation of the unique identifier for that intersection point, which is shown by the perimetrically-labeled grid patterns of Muller and Krupnick. *See* FF 5. For example, labeling the intersection point found at "d8" in the grid of Muller so that it actually reads "d8" merely adds the label "d8" to an intersection point that is already known to a person of ordinary skill in the art to represent the intersection point identified as "d8." Hence, the individual labeling of an intersection point in the grid pattern of the surgical drape of Muller and Krupnick adds nothing more to the grid pattern than merely a local symbol to represent an already known unique identifier of

that intersection point. Whether a grid pattern has individual labeled intersection points or an abbreviated labeling system using the letters and numbers along the perimeter of the pattern, as that of Muller and Krupnick, the structure of the surgical drape remains the same. In other words, the individual labeling of the intersection points does not change the function of the surgical drape of Muller and Krupnick. Claiming individual labeling of each intersection point does not impart patentable distinction because the difference is “useful and intelligible only to the human mind.” See *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (quoting *In re Bernhart*, 417 F.2d 1395, 1399 (CCPA 1969)).

Lastly, Appellant argues that neither Muller nor Krupnick discloses a “sterile” drape. Br. 4. We find Appellant’s argument unpersuasive because Muller specifically discloses the use of an antiseptic. Muller, col. 6, ll. 14-17 and fig. 4. See also, Ans. 5.⁵ Even were it assumed that Muller and Krupnick do not expressly disclose a sterile drape, it would have been obvious to use a sterile drape in a surgical procedure.

In view of the foregoing, we sustain the Examiner’s rejection of claim 30 along with claims 32, 34-38, 41-43, 47, 48, 57, 59, 61, and 71-75, standing or falling with claim 30. Inasmuch as we found those arguments unpersuasive, we likewise find them unpersuasive for the rejection of claims 39, 40, 44, 59, and 68-70 as unpatentable over the combined teachings of Muller, Krupnick, and Mosby. Therefore, we sustain the Examiner’s rejection of claims 39, 40, 44, 59, and 68-70 over the combined teachings of Muller, Krupnick, and Mosby.

⁵ Throughout the opinion we refer to the Examiner’s Answer mailed Apr. 8, 2008 as “Ans.”.

Issue (2)

Appellant's Specification does not expressly define the term "cutout" or otherwise indicate that this term is used in a manner other than its ordinary and customary meaning. Accordingly, we construe this term in accordance with its ordinary and customary meaning. We find that an ordinary and customary meaning of the term "cutout," that is most consistent with the Specification and the understanding of those of ordinary skill in the art is, "something cut out or off from something else." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (10th Ed. 1997). As pointed out by Appellant, the opening 40 of Krupnick is formed as die-cut lines in the sheet 20. Br. 5. *See also*, Krupnick, col. 5, ll. 17-20 and fig. 2. As noted above, a "cutout" requires something to be *cut out or off* from something else. In this case, the opening 40 in Krupnick has been cut *in or into* the sheet 20. Similarly, when a biopsy needle enters the surgical drape of Krupnick, as the Examiner proposes, the needle cuts *in or into* the surgical drape. Accordingly, we agree with Appellant that the opening 40 of Krupnick does not constitute a "cutout."

For the foregoing reasons the rejection of claims 49, 53-56 and 67 cannot be sustained. With respect to claims 50, 62 and 63, the teachings of Mosby do not remedy the deficiency of Muller and Krupnick as described above. Accordingly, the rejection of claims 50, 62 and 63 likewise cannot be sustained.

Issue (3)

Claims 45 and 51 require that the "sheet comprises a cylindrical portion *adapted to* fit over a finger." Mosby does not specifically disclose

that its localization device is “*adapted to fit over a finger.*” The use of the term “adapted to” means that the claimed sheet “is capable” of being fitted over a finger. Although Mosby uses a human breast as an example to explain the function of the localization device, as correctly pointed out by the Examiner, Mosby also refers to using the localization device on “human body parts.” *See* Ans. 7. *See also, e.g.,* Mosby, col. 5, ll. 38-40. As such, we do not find that Mosby is strictly limited to usage on a human breast, as Appellant appears to imply. As found above, the localization device of Mosby includes a cylindrical portion and a hemispherical end portion located at one end of the cylindrical portion. FF 7. Similarly, a finger includes a cylindrical portion and a hemispherical end portion located at one end of the cylindrical portion. *See* Figures 29 and 30 of Appellant’s Drawings. Moreover, the sheet of Mosby is a pliable sheet that conforms to the shape of the subject body part, and as such, can take the shape of the body part. *See* FF 6. Accordingly, we conclude that because the surgical drape of Muller, Krupnick and Mosby is pliable, it is capable of being fitted over a finger. Moreover, with respect to claim 51, we note that it is broader than claim 45 in the sense that the claimed sheet includes a “cylindrical portion *adapted to fit over a finger or other appendage.*”⁶ *Emphasis added.* We find that the human breast in Mosby constitutes an “appendage.” In

⁶ We find that an ordinary and customary meaning of the term “appendage” that is most consistent with the Specification and the understanding of those of ordinary skill in the art is “a usually projecting part of an animal or a plant body that is typically smaller and of less functional importance than the main part to which it is attached.” MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY (10th Ed. 1997).

conclusion, for the foregoing reasons, the rejection of claims 45 and 51 over the combined teachings of Muller, Krupnick, and Mosby is sustained.

Finally, with respect to claims 46 and 52, as shown in Figure 4 of Mosby, the localization device of Mosby includes a cylindrical portion and a hemispherical end portion located at one end of the cylindrical portion. FF 7. As such, the rejection of claims 46 and 52 over the combined teachings of Muller, Krupnick, and Mosby is likewise sustained.

Issue (4)

Each of claims 64-66 requires the limitation of “applying a sterile surgical drape to a patient by *unrolling* a cylindrical portion of the sterile surgical drape onto an extremity, finger or other appendage of the patient.” Emphasis added.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In this case, we find that the Examiner has not made any factual finding as to the step of “unrolling” as called for in each of claims 64-66. Accordingly, we find the Examiner’s legal conclusion of obviousness is not supported by facts, and thus, cannot stand. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) (holding that “[t]he legal conclusion of obviousness must be supported by facts. Where the legal conclusion is not supported by facts it cannot stand.”). Therefore, we are constrained to reverse the rejection of claims 64-66 over the combined teachings of Muller, Krupnick, and Mosby.

CONCLUSIONS

1. The Examiner has not erred in concluding that the combined teachings of Muller and Krupnick would have prompted a person of ordinary skill in the art to provide a unique radio-opaque label at each intersection point of a plurality of intersections of a radio-opaque pattern.
2. The combined teachings of Muller and Krupnick do not disclose a sterile surgical drape having “a central cutout,” as called for by independent claims 53 and 62.
3. The combined teachings of Muller, Krupnick, and Mosby disclose a “cylindrical portion adapted to fit over a finger,” as per claims 45 and 51, and a “hemispherical end portion located at one end of the cylindrical portion,” as per claims 46 and 52.
4. The Examiner erred in concluding that the combined teachings of Muller, Krupnick, and Mosby disclose “applying a sterile surgical drape to a patient by unrolling a cylindrical portion of the sterile surgical drape onto an extremity, finger or other appendage of the patient,” as called for by independent claim 64.

DECISION

The Examiner’s decision is affirmed as to claims 30, 32, 34-48, 51, 52, 57, 59, 61, and 68-75 and reversed as to claims 49, 50, 53-56, and 62-67.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART

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